



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application

Inventor(s): Steve Mitchell

Appln. No.: 10/684,668

Confirm. No.: 3396

Filed: October 14, 2003

Title: ARTIFICIAL VERTEBRAL DISK
REPLACEMENT IMPLANT WITH
CROSSBAR SPACER AND METHOD

PATENT APPLICATION

Art Unit: 3738

Examiner: Bruce Edward Snow

Atty. Docket No.: KLYCD-05008US1

Customer No. 23910

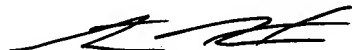
DECLARATION OF STEVE MITCHELL UNDER 37 C.F.R. § 1.131

1. My name is Steve Mitchell.
2. This declaration is submitted under 37 C.F.R. § 1.131.
3. I understand that I have a duty to disclose to the U.S. Patent and Trademark Office all information I know to be material to patentability as defined in 37 C.F.R. § 1.56.
4. I am an employee of St. Francis Medical Technologies, Inc., the assignee of the above U.S. patent application and specialize in development of spinal implant devices.
5. I am the sole inventor of the above U.S. patent application.
6. I designed a prototype embodiment of the invention described in the above U.S. patent application in March 2002.
7. I attended an internal meeting in May 2002 where the prototype was shown to a research and development team.
8. I have viewed photographs labeled as Exhibits A-D.
9. I verify that Exhibits A and C are lateral anterior to posterior views of an artificial spinal model with the prototype inserted.
10. I verify that Exhibits B and D are frontal anterior views of an artificial spinal model with the prototype inserted.

11. I verify that Exhibits A and C show the prototype implant described in the specification and shown in Figure 3 of the above application which incorporates the crossbar shown in Figures 2A-2D of the above application located between upper and lower plates inserted between two adjacent vertebrae of an artificial spinal model as represented in Figure 4 of the above application.
12. For convenience, Claim 1 of the above application is set out below with elements (a)-(j) identified as follows:
An implant comprising:
 - (a) a first piece having a first socket;
 - (b) a second piece having a second socket; and
 - (c) a crossbar member comprising:
 - (d) a first beam; and
 - (e) a second beam
 - (f) wherein the length of the second beam is configured transversely to the length of the first beam;
 - (g) wherein the crossbar is at least partially received in the first socket and the second socket;
 - (h) wherein at least the first piece does not fuse to the crossbar;
 - (j) wherein at least the first piece is capable of pivoting about the crossbar member to accommodate at least one of flexion, extension and lateral bending.
13. The prototype had a first piece having a first socket as claimed in Claim 1, element (a) and shown in Exhibit D.
14. The prototype had a second piece having a second socket as claimed in Claim 1, element (b) and shown in Exhibit D.
15. The prototype had a crossbar member as claimed in Claim 1, element (c) and shown in Exhibits A, C and D.
16. The crossbar had a first beam as claimed in Claim 1, element (d) and shown in Exhibit D.
17. The crossbar had a second beam as claimed in Claim 1, element (e) and shown in Exhibit D.
18. The length of the second beam of the crossbar was configured transversely to the length of the first beam as claimed in Claim 1, element (f) and shown in Exhibit D.
19. The crossbar was partially received in the first socket and the second socket as claimed in Claim 1, element (g) and shown in Exhibit A.
20. The prototype was designed such that the crossbar did not fuse to the first piece as claimed in Claim 1, element (h) and shown in Exhibits A and C.

21. The first piece was capable of pivoting about the crossbar member to accommodate flexion, extension and lateral bending as claimed in Claim 1, element (j) and shown in Exhibits A and C.
22. The prototype was tested in a functional setting by inserting the prototype in the model.
23. The prototype was tested in a functional setting by inserting the prototype in a cadaver.
24. Based on information or belief, between October 3, 2002 and October 29, 2002 the attorneys for St Francis Medical Technologies Inc. responsible for the above patent application spent parts of eight days and in combination in excess of 25 hours preparing the above application.
25. I verify that the design, construction and reduction to practice of this prototype took place in the United States of America.
26. The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any resulting registration, declares that the facts set forth in this declaration are true; all statements made of his own knowledge are true; and all statements made on information and belief are believed to be true.

6-8-06
Date


Signature

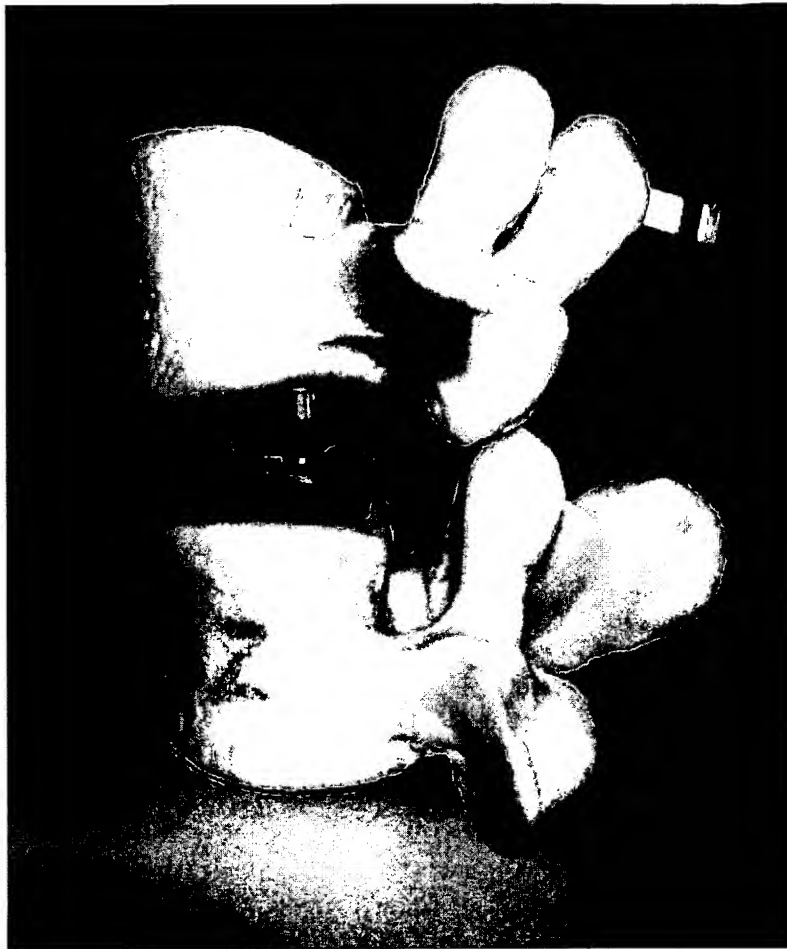


EXHIBIT A



EXHIBIT B

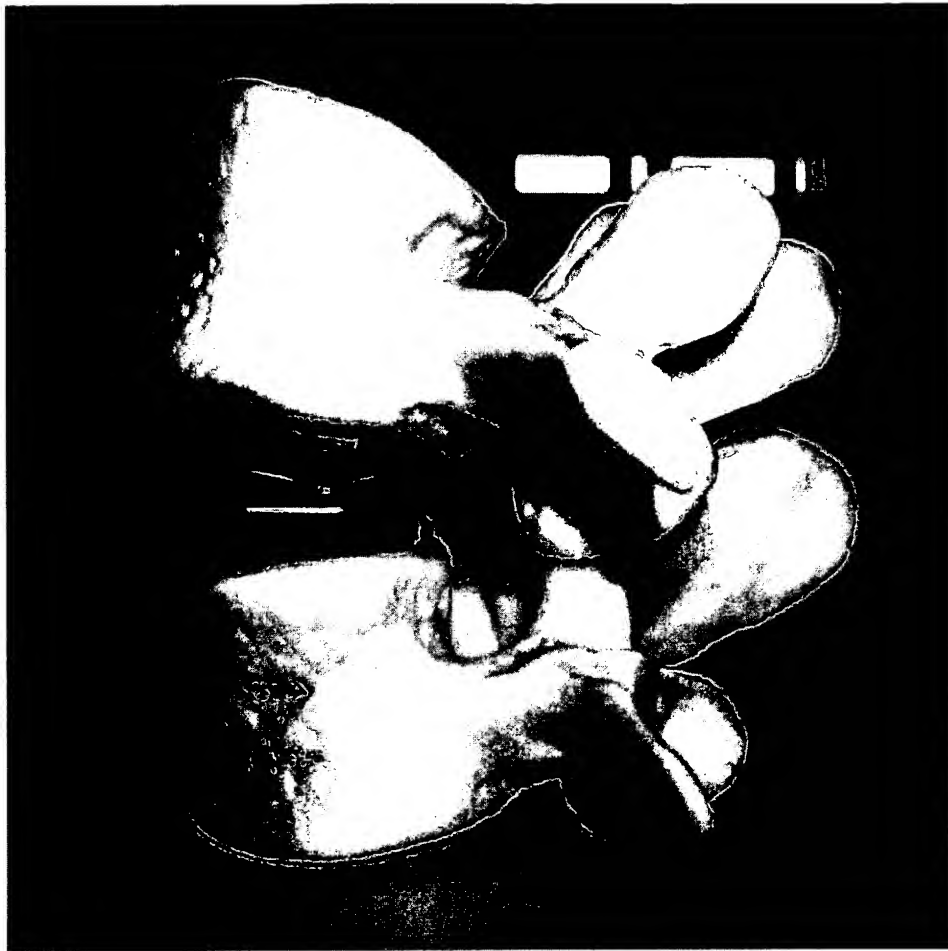


EXHIBIT C

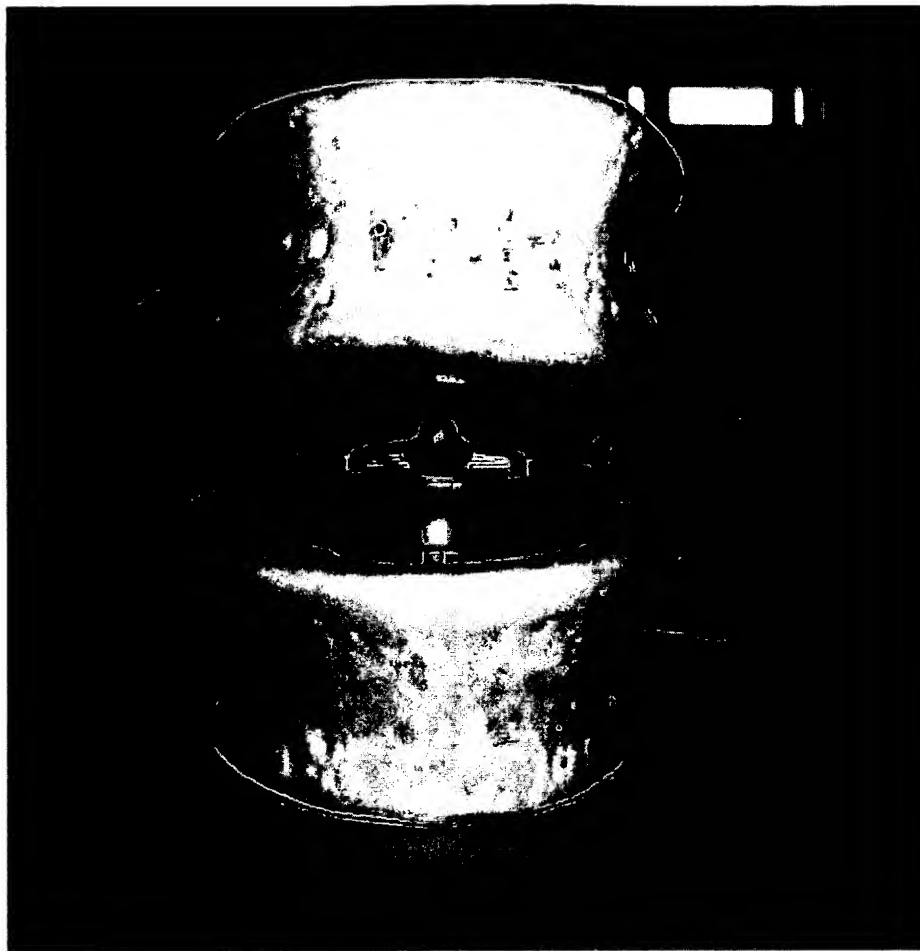


EXHIBIT D